

Remarks/Arguments

The present amendment amends the Abstract; amends the Drawing; cancels claims 2-31, 34-38, 43, 45-77; amends claims 32, 33, 39 and 57; and adds new claims 78-81. The amendment is without prejudice to future prosecution.

The Abstract and Drawings were amended to correct deficiencies noted by the examiner. The amendment to the Abstract removes the first of two provided paragraphs. The amendment to the Drawings provides larger and clearer letters, numbers, and reference characters for Figures 1, 2 and 6.

Claims 32 and 33 were amended to be consistent with the elected species, and Claim 39 was amended to be consistent with the cancellation of claims 34-37. Amended claim 39 refers to either claim 32 or 33.

New claims 78-81 are directed to a nucleotide sequence encoding for SEQ ID NO: 7068 operably linked to a heterologous regulatable promoter (claims 78 and 79) and a host cell containing such nucleic acid (claims 80 and 81). SEQ ID NO: 7068 provides the amino acid sequence of the protein encoded by SEQ ID NO: 6068.

35 U.S.C. § 102 (b) and (e)

Claims 34, 37, 39 and 42 stand rejected as allegedly anticipated under 35 U.S.C. § 102 (b) based on Kiebler et al. (Nature Vol. 348, 1990, pp. 610-616); and claims 34, 35, and 39-42 stand rejected as allegedly anticipated under 35 U.S.C. § 102 (e) based on Weinstock et al. (U.S. Patent No. 6,747,137). Claims 34, 35 and 37 were canceled without prejudice to future prosecution. Claim 39 was amended to remove reference to claims 34, 35 and 37. Reconsideration is respectfully requested.

35 U.S.C. § 101 (Non-Statutory Subject Matter)

Claims 34 and 35 stand rejected as allegedly directed to non-statutory subject matter. The examiner argues that these claims read on naturally occurring sequences. Claims 34 and 35 were canceled without prejudice to future prosecution.

Serial No.: 10/032,585

Case No.: E1016Y

Amendments to the Drawings:

The drawings were revised to correct the defects noted by the Examiner.

Attachment: Replacement Sheets

35 U.S.C. §§ 101 and 112 (Utility)

Claims 32-42 stand rejected under 35 U.S.C. §§ 101 and 112. The examiner argues that the application allegedly fails to provide a specific, substantial or well established utility for the claimed subject matter. The rejection is respectfully traversed.

It is respectfully submitted that the application provides credible support for at least two specific and substantial utilities: (1) utilities based on SEQ ID NO: 6068 coding for an essential gene; and (2) diagnostic utilities based on SEQ ID NO: 6068 or the encoded protein.

(1) Utilities Based on SEQ ID NO: 6068 Coding for an Essential Gene

The application identifies SEQ ID NO: 6068 as an essential gene using the GRACE methodology. The GRACE methodology inactivates one target allele and places a second target allele under control of a regulatable promoter. SEQ ID NO: 6068 is listed in Table II as a gene demonstrated to be essential when conditionally expressed under the tetracycline repression system in the respective GRACE strains or when the gene encoding the transactivator protein is excised in the respective GRACE strain in a 5-FOA assay. (The present application at page 36, lines 29-32.)

The patent office has the initial burden of challenging a presumptively correct assertion of utility. The rejection attempts to discount the provided results by arguing that result were only provided under a specific set of *in vitro* culture conditions and that application fails to provide biological, functional and structural properties needed to intelligently screen for active drugs.

It is respectfully that the provided *in vitro* results reasonably correlate to *in vivo* importance. A reasonable correlation suffices to show practical utility. (*Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). A “rigorous correlation” does need to be shown to establish practical utility. *Id.* The rejection fails to provide any evidence indicating the lack of a reasonably correlation between the GRACE methodology and *in vivo* importance.

In addition, the application provides a structure for the target and illustrates techniques that can be used to both identify compounds binding to the target and to evaluate the effectiveness of compounds. The structure for the protein target is provided by SEQ ID NO: 7068.

The application provides examples of assays that can be used to identify compounds capable of binding to a protein target. (The present application, Section 5.5.1, pages 93-94.)

The application describes the use of sensitized cells to screen for compounds active at a particular target gene. (The present application, Section 5.5.2, on pages 102-107.) Sensitized cells can be obtained using a GRACE strain to control the expression of an identified essential gene. Compounds affecting the identified target pathway can be identified by the difference in the effect of the compound on a sensitized versus non-sensitized cell.

(2) Diagnostic Utilities Based on SEQ ID NO: 6068 or the Encoded Protein

The rejection argues that diagnostic utilities mentioned in the application are not specific to SEQ ID NO: 6068 because such utilities generally apply to any nucleic acid contained in *C. albicans*. It respectfully submitted that the ability of other sequences from *C. albicans* to have diagnostic utility does not take away from the diagnostic utilities of SEQ ID NO: 6068.

SEQ ID NO: 6068, and the encoded protein, appears to be unique for the pathogen *C. albicans*. As such, the nucleic acid and encoded protein have diagnostic applications specifically based on the particular sequences.

In contrast to sequences related to SEQ ID NO: 6068, nucleic acids in general do not have diagnostic applications for *C. albicans*. For example, nucleic acids encoding human proteins would not be useful for specifically detecting *C. albicans*.

35 U.S.C. § 112 (Written Description)

Claims 34 and 37-42 stand rejected as allegedly failing to comply with the written description requirement provided by 35 U.S.C. § 112. The examiner argues that the specification does not provide a representative number of species given the large breadth of the claimed genus which includes sequences from different organisms.

Claims 34, 37, and 38 were canceled without prejudice to future prosecution. Claim 39 was amended to remove reference to claims 34 and 37. Reconsideration of the rejection is respectfully requested.

Serial No.: 10/032,585
Case No.: E1016Y

35 U.S.C. § 112 (Clarity)

Claims 32, 33, 35 and 36 stand rejected as allegedly indefinite. The rejection is based on reference to "comprises" and "consisting" in claim 32 and reference to "condition" in claim 35. Claim 32 was amended as suggested by the examiner to reference "comprising" and "consists". Claim 35 was canceled without prejudice to future prosecution. Reconsideration of the rejection is respectfully requested.

Accordingly the claims are in condition for allowance. Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By Sheldon O. Heber
Sheldon O. Heber
Reg. No. 38,179
Attorney for Applicants

Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907
(732) 594-1958